K093749

5. 510(k) Summary

Submitter/Contact Person	H. Carl Jenkins The **Wood Burditt** Group FDA Regulatory Counseling 10 E. Scranton Avenue, Suite 201 Lake Bluff, IL 60044 (ph) (847) 234-7500 x 205 (fax) (847) 574-0728 (email) hcjenkins@woodburditt.com DEC - 6 2010
Applicant	GC America, Inc. 3737 W. 127th Street Alsip, IL 60803 800.323.3386 x4042 708.897.4042 708.897.4031 (fax)
Manufacturer	GC CORPORATION. 76−1 HASUNUMA−CHO, ITABASHI−KU TOKYO 174−8585 JAPAN
Sterilization Facility	RADIA INDUSTRY CO., LTD 168 OOYAGI, TAKASAKI GUNNMA 370−0072 JAPAN
Device Name	GC Aadva Implant System
Common Name	Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutment
Classification	Class II Procode DZE Regulation: 21 CFR 872.3640

Identification of Predicates and Summary of Substantial Equivalence	The GC Aadva Implant System is substantially equivalent with respect to the intended use, design, risks, device characteristics and performance aspects to numerous cleared devices, including: <u>510(k) / Product / Manufacturer</u> - K072425 / JNE IMPLANT SYSTEM / GC AMERICA, INC. - K971196 / ENDOPORE ENDOSSEOUS DENTAL IMPLANT SYSTEM / INNOVA CORP. - K002513 / ASTRA TECH IMPLANTS - DENTAL SYSTEM / ASTRA TECH, INC. - K033984 / STRAUMANN DENTAL IMPLANT SYSTEM / INSTITUT STRAUMANN AG The GC Aadva Implant System is comparable to the GC JNE Implant System (K072425) in technological characteristics. More specifically, the GC Aadva Implant System and the GC JNE Implant System have the same component material, chemical composition, body type, design shape, engaging method, implant surface treatment and dimensions (lengths and diameters). The GC Aadva Implant System and GC JNE Implant System also have the same indications for use.
Device Description	The GC Aadva Implant System is an endosseous dental implant made of Ti-6Al-4V ELI alloy and consists of several components. Geometrically, the implant is screw-type. An abutment is connected to the implant through a tapered-joint. Implants are treated with sandblast and acid etching using scanning electron microscopy (SEM). The device functions by being surgically implanted in the bone of the upper or lower jaw arches in order to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function. With regard to the scientific concepts that form the basis for the device, root-form endosseous dental implant devices are characterized by four geometrically distinct types: basket, screw, solid cylinder, and hollow cylinder. The GC Aadva

	Implant System is a "screw" endosseous dental implant. With regard to the physical and performance characteristics of the GC Aadva Implant System, the design shape, engaging method, implant surface treatment and dimensions (lengths and diameters) are the same as the lawfully marketed predicate GC JNE Implant System.
Intended Use and Indications	The GC Aadva Implant System is a titanium alloy screw-type endosseous dental implant and endosseous dental implant abutment, which is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function. The GC Aadva Implant System is intended for immediate loading only when good primary stability is achieved and with appropriate occlusal loading.
Performance Testing	**I. <u>Nonclinical Data</u>** Bench testing that studied the solubility, the corrosion and electrochemical properties of the metals, the cytotoxicity, and the fatigue of the GC Aadva Implant System was conducted. Testing indicated that Ti-6Al-4V alloy is estimated to be a corrosion resistant material and not cytotoxic. Furthermore, testing indicated that Ti-6Al-4V ELI alloy has acceptable strength according to the fatigue test results. Additionally, the packaging system for sterilized products and non-sterile components of GC Aadva Implant System is the same as that of JNE Implant System (K072425) in constituent materials and the structure, which has been validated according to ISO 11607-1. Animal testing that studies titanium alloy's suitability for surgical implant use was conducted. Results indicate that Ti-6Al-4V ELI alloy is suitable for surgical implant use. Also, animal testing was conducted to determine the compatibility of the GC Aadva Implant System to bone tissue. Results indicate that Ti-6Al-4V ELI alloy is compatible to bone tissue. Bench testing was conducted in accordance with the

	procedures outlined in the *Guidance for Industry and FDA Staff Class II -- Special Controls Guidance Document: Root-form Endosseous Dental Implants.* **II. Clinical Data** No clinical test data is being submitted with this 510(k). **III. Conclusions drawn from clinical and nonclinical data indicating that the new device is safe and effective for its intended use and performs as well or better than predicate device.** Performance testing data indicates that the new device is safe and effective for its intended use and performs as well or better than predicate device. Specifically, testing demonstrates that component material in the subject device is the same as the component material in a predicate device, and conforms to relevant ISO and ASTM standards. Bench testing conducted in accordance with the procedures outlined in the *Guidance for Industry and FDA Staff Class II -- Special Controls Guidance Document: Root-form Endosseous Dental Implants* demonstrates that this device meets the mechanical properties recommendations by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GC America, Incorporated
C/O Mr. Carl Jenkins
Wood Burditt Group
10 E. Scranton Avenue, Suite 201
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DEC - 6 2010

Re: K093749
Trade/Device Name: GC Aadva Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 24, 2010
Received: November 26, 2010

Dear Mr. Jenkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

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510(k) Number (if known): K093749

Device Name: GC Aadva Implant System

Indications for Use:

The GC Aadva Implant System is a titanium alloy screw-type endosseous dental implant and endosseous dental implant abutment, which is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for a prosthetic device, such as an artificial tooth, in order to restore a patient's chewing function.

The GC Aadva Implant System is intended for immediate loading only when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices